Docket No. 15611-7032/CGAB-210-USA

Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Commissioner for Patents and Trademarks, Washington D.C. 20231.

Dated: April 12, 2002 Name of Person Certifying: David Maher
Printed Name: David W. Maher

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Deborah KNUTZON, *et al.*
Filing Date: August 5, 1999
Serial No.: 09/367, 013
Assignee: Calgene, Inc./Abbott Laboratories
Examiner: N. Nashed
Group Art Unit: 1652
Title: Methods and Compositions for Synthesis of Long Chain Polyunsaturated Fatty Acids

Commissioner for Patents
Washington, D.C. 20231

RESPONSE/AMENDMENT

In response to the Office Action of October 12, 2001, Applicants respectfully request reconsideration of the above-identified application in view of the following amendments and remarks. A three month extension of time is requested.

IN THE CLAIMS

Please cancel claims 65-160 and 187 without prejudice to pursuit in a subsequent application.

Please add the following claims:

--189. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid comprising the sequence depicted in SEQ ID NO: 1, said nucleic acid operably linked to transcription and translation control signals functional in said cell, wherein a polypeptide encoded by said nucleic acid is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

190. The method of claim 189, wherein said cell is a fungal cell.

191. The method of claim 190, wherein said fungal cell is a yeast cell.

192. The method of claim 189, wherein at least one of said transcription and translation control signals is endogenous to said microbial cell.

193. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid with at least 50% homology to the sequence depicted in SEQ ID NO: 1, said nucleic acid operably linked to transcription and translation control signals functional in said cell, wherein a polypeptide encoded by said nucleic acid forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

194. The method of claim 193, wherein said cell is a fungal cell.

195. The method of claim 194, wherein said fungal cell is a yeast cell.

196. The method of claim 193, wherein at least one of said transcription and translation control signals is endogenous to said microbial cell.

197. The method of claim 193, wherein said nucleic acid has at least 60% homology to the sequence depicted in SEQ ID NO: 1.

198. The method of claim 193, wherein said nucleic acid has at least 80% homology to the sequence depicted in SEQ ID NO: 1.

199. The method of claim 193, wherein said nucleic acid has at least 90% homology to the sequence depicted in SEQ ID NO: 1.

200. The method of claim 193, wherein said nucleic acid has at least 95% homology to the sequence depicted in SEQ ID NO: 1.

201. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid operably linked to transcription and translation control signals functional in said cell, wherein said nucleic acid is a deletion mutant of the nucleic acid depicted in SEQ ID NO: 1, wherein a polypeptide encoded by said nucleic acid forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

202. The method of claim 201, wherein said cell is a fungal cell.

203. The method of claim 202, wherein said fungal cell is a yeast cell.

204. The method of claim 201, wherein at least one of said transcription and translation control signals is endogenous to said microbial cell.

205. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a recombinant microbial cell comprising a polypeptide comprising the amino acid sequence depicted in SEQ ID NO:2, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

206. The method of claim 205, wherein said cell is a fungal cell.

207. The method of claim 206, wherein said fungal cell is a yeast cell.

208. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a recombinant microbial cell comprising a polypeptide with at least 60% homology to the sequence depicted in SEQ ID NO: 2, wherein said polypeptide forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

209. The method of claim 208, wherein said polypeptide has at least 80% homology to the sequence depicted in SEQ ID NO: 2.

210. The method of claim 208, wherein said polypeptide has at least 90% homology to the sequence depicted in SEQ ID NO: 2.

211. The method of claim 208, wherein said polypeptide has at least 95% homology to the sequence depicted in SEQ ID NO: 2.

212. The method of claim 208, wherein said cell is a fungal cell.

213. The method of claim 212, wherein said fungal cell is a yeast cell.

214. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid that hybridizes to the complement of the sequence depicted in SEQ ID NO: 1, said nucleic acid operably linked to

transcription and translation control signals functional in said cell, wherein a polypeptide encoded by said nucleic acid forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

215. A method for producing oil with an altered fatty acid profile comprising extracting oil from the microbial cell produced according to the method of claim 189.

216. The method of claim 215, further comprising purifying a component of said oil.

217. The method of claim 216, wherein said component is a phospholipid.

218. The method of claim 216, wherein said component is a sulfolipid.

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224. The method of claim 216, wherein said component is a fatty acid.

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226. The method of claim 225, further comprising purifying a component of said oil.

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254. The method of claim 246, wherein said component is a fatty acid.

255. A method for producing oil with an altered fatty acid profile comprising extracting oil from the microbial cell produced according to the method of claim 205.

256. The method of claim 255, further comprising purifying a component of said oil.

257. The method of claim 256, wherein said component is a phospholipid.

258. The method of claim 256, wherein said component is a sulfolipid.

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266. The method of claim 265, further comprising purifying a component of said oil.

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276. The method of claim 275, further comprising purifying a component of said oil.

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284. The method of claim 276, wherein said component is a fatty acid.

REMARKS

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The Examiner alleged that the drawings were objected to, and that the defects were noted on the attached PTO-498. However, the attached PTO-498 indicated that the drawings were approved. Clarification is requested.

The Examiner asserted that the application failed to comply with the requirements of 37 CFR 1.821-1.825 for the reasons set forth on an allegedly attached Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. However, no such Notice to Comply was attached. The Examiner is requested to provide Applicants with any Notice to Comply that has been issued in this case so that it may be properly addressed.

The Examiner's comments regarding trademark usage are noted. Applicants choose to defer addressing these matters until such time as otherwise allowable subject matter is reached.

The double patenting rejections

Claims 65, 66, 94, 99, 100 and 187 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-10 and 15 of U.S. Patent No. 6,136,574 ('574), claim 11 of U.S. Patent No. 6,075,183 ('183), and claims 12-20 and 26-30 of U.S. Patent No. 5,968,809 ('809).

Insofar as claims 65, 66, 94, 99, 100 and 187 have been cancelled, these rejections are moot, and are otherwise traversed. Applicants request that these rejections be held in abeyance until such time as otherwise allowable subject matter has been achieved.

The rejections under 35 U.S.C. 112, first paragraph

The Examiner rejected claims 65, 66, 93, 94, 99, 100 and 187 under 35 U.S.C. 112, first paragraph, as lacking sufficient written description. The Examiner objected to the lack of sufficient representative species, and asserted that many proteins existed comprising the fragments recited in the claims without desaturase activity, but provided no examples. Claims 65, 66, 93, 94, 99, 100 and 187 have been cancelled, rendering this rejection moot.

Claims 189-284 have been added, and are fully described in the application as filed. Support for claims 189-284 can be found throughout the application as filed, for example in claims 65, 66, 93, 94, 99, 100 and 187 as filed, at page 4 line 18 through page 9 line 11, at page 12 line 11 to page 15 line 17, at page 17 line 16 through page 29 line 4, at page 32 line 21 to page 33 line 14, in Examples 2-3 at page 47-50, Examples 5-7 at pages 51-60, and Table 2. No new matter is added.

Claims 65, 66, 93, 94, 99, 100 and 187 were also rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner objected to the claim scope regarding all possible polypeptides comprising the recited fragments. The Examiner's statements regarding purification of oil and components are traversed; the application is replete with examples of oil purification from microbes and purification of fractions therefrom. The support is as recited above. Claims 65, 66, 93, 94, 99, 100 and 187 have been cancelled, rendering this rejection moot.

Claims 189-284 are fully supported by the description in the application and are fully enabled. The claim terms to which the Examiner has objected are absent from claims 189-284. The rejections under 35 USC 112, first paragraph are moot.

The rejection under 35 U.S.C. 112, second paragraph

The Examiner rejected claims 65, 66, 93, 94, 99, 100 and 187 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner objected to the phrase "altering long chain fatty acid" in claims 65 and 187 on the grounds that "long" and "altering" are not defined, with

the Examiner attributing an expansive definition to the term "altering," and failing to note the numerous ways described in the application by which the claimed method is taught to alter fatty acid biosynthesis. The Examiner also objected to the phrase "oil or fraction thereof" in claims 99 and 100, finding "fraction thereof" unclear. While Applicants traverse the Examiner's rejection and assert that one of skill in the art would find such terms clear and definite, claims 65, 66, 93, 94, 99, 100 and 187 have been cancelled, rendering this rejection moot. Claims 189-284 lack the terms to which the Examiner objected. The rejections under 35 USC 112, second paragraph are therefore moot.

The rejection under 35 U.S.C. 102(e)

The Examiner rejected claim 99 under 35 U.S.C. § 102(e) over U.S. Pat. No. 5,670,540 to Horrobin et al. ("'540"). Cancellation of claim 99 renders this rejection moot at this time. However, Applicants traverse the Examiner's assertions regarding '540. Applicants claim methods of producing microbial cells having an altered fatty acid profile, and methods of obtaining microbial oils and fractions thereof. '540 deals with forming triglycerides having abnormal arrangements of fatty acids that are not found in nature at all. See col. 4 lines 12-17. '540 also discusses compositions having high levels of LGG (see col. 4). Nowhere does '540 discuss expression of Δ6 desaturases in microbial cells so as to alter their fatty acid profile, or the production of oil from such cells, or the purification of a component therefrom.

CONCLUSION

Accordingly, in view of the above remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (408) 849-4908.

DATE: April 12, 2002

Respectfully submitted,

By: _____

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Docket No. 15611-7032/CGAB-210-USA

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Dated: April 12, 2002 Name of Person Certifying: David W. Maher Printed Name: David W. Maher

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Deborah KNUTZON, *et al.*
Filing Date: August 5, 1999
Serial No.: 09/367, 013
Assignee: Calgene, Inc./Abbott Laboratories
Examiner: N. Nashed
Group Art Unit: 1652
Title: Methods and Compositions for Synthesis of Long Chain Polyunsaturated Fatty Acids

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IN THE CLAIMS

Please cancel claims 65-160 and 187 without prejudice to pursuit in a subsequent application.

Please add the following claims:

--189. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid comprising the sequence depicted in SEQ ID NO: 1, said nucleic acid operably linked to transcription and translation control signals functional in said cell, wherein a polypeptide encoded by said nucleic acid is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

190. The method of claim 189, wherein said cell is a fungal cell.

191. The method of claim 190, wherein said fungal cell is a yeast cell.

192. The method of claim 189, wherein at least one of said transcription and translation control signals is endogenous to said microbial cell.

193. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid with at least 50% homology to the sequence depicted in SEQ ID NO: 1, said nucleic acid operably linked to transcription and translation control signals functional in said cell, wherein a polypeptide encoded by said nucleic acid forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

194. The method of claim 193, wherein said cell is a fungal cell.

195. The method of claim 194, wherein said fungal cell is a yeast cell.

196. The method of claim 193, wherein at least one of said transcription and translation control signals is endogenous to said microbial cell.

197. The method of claim 193, wherein said nucleic acid has at least 60% homology to the sequence depicted in SEQ ID NO: 1.

198. The method of claim 193, wherein said nucleic acid has at least 80% homology to the sequence depicted in SEQ ID NO: 1.

199. The method of claim 193, wherein said nucleic acid has at least 90% homology to the sequence depicted in SEQ ID NO: 1.

200. The method of claim 193, wherein said nucleic acid has at least 95% homology to the sequence depicted in SEQ ID NO: 1.

201. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid operably linked to transcription and translation control signals functional in said cell, wherein said nucleic acid is a deletion mutant of the nucleic acid depicted in SEQ ID NO: 1, wherein a polypeptide encoded by said nucleic acid forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

202. The method of claim 201, wherein said cell is a fungal cell.

203. The method of claim 202, wherein said fungal cell is a yeast cell.

204. The method of claim 201, wherein at least one of said transcription and translation control signals is endogenous to said microbial cell.

205. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a recombinant microbial cell comprising a polypeptide comprising the amino acid sequence depicted in SEQ ID NO:2, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

206. The method of claim 205, wherein said cell is a fungal cell.

207. The method of claim 206, wherein said fungal cell is a yeast cell.

208. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a recombinant microbial cell comprising a polypeptide with at least 60% homology to the sequence depicted in SEQ ID NO: 2, wherein said polypeptide forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

209. The method of claim 208, wherein said polypeptide has at least 80% homology to the sequence depicted in SEQ ID NO: 2.

210. The method of claim 208, wherein said polypeptide has at least 90% homology to the sequence depicted in SEQ ID NO: 2.

211. The method of claim 208, wherein said polypeptide has at least 95% homology to the sequence depicted in SEQ ID NO: 2.

212. The method of claim 208, wherein said cell is a fungal cell.

213. The method of claim 212, wherein said fungal cell is a yeast cell.

214. A method for producing a microbial cell with an altered fatty acid profile comprising:

culturing a microbial cell comprising a recombinant nucleic acid that hybridizes to the complement of the sequence depicted in SEQ ID NO: 1, said nucleic acid operably linked to

transcription and translation control signals functional in said cell, wherein a polypeptide encoded by said nucleic acid forms a monounsaturated bond between carbons 5 and 6 of a fatty acid as numbered from a carboxy terminus thereof, wherein said polypeptide is expressed in sufficient amount in said cell to alter the fatty acid profile of said cell.

215. A method for producing oil with an altered fatty acid profile comprising extracting oil from the microbial cell produced according to the method of claim 189.

216. The method of claim 215, further comprising purifying a component of said oil.

217. The method of claim 216, wherein said component is a phospholipid.

218. The method of claim 216, wherein said component is a sulfolipid.

219. The method of claim 216, wherein said component is a glycolipid.

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221. The method of claim 216, wherein said component is a monoacylglycerol.

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223. The method of claim 216, wherein said component is a triacylglycerol.

224. The method of claim 216, wherein said component is a fatty acid.

225. A method for producing oil with an altered fatty acid profile comprising extracting oil from the microbial cell produced according to the method of claim 193.

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244. The method of claim 236, wherein said component is a fatty acid.

245. A method for producing oil with an altered fatty acid profile comprising extracting oil from the microbial cell produced according to the method of claim 202.

246. The method of claim 245, further comprising purifying a component of said oil.

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The Examiner rejected claims 65, 66, 93, 94, 99, 100 and 187 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner objected to the phrase "altering long chain fatty acid" in claims 65 and 187 on the grounds that "long" and "altering" are not defined, with

the Examiner attributing an expansive definition to the term "altering," and failing to note the numerous ways described in the application by which the claimed method is taught to alter fatty acid biosynthesis. The Examiner also objected to the phrase "oil or fraction thereof" in claims 99 and 100, finding "fraction thereof" unclear. While Applicants traverse the Examiner's rejection and assert that one of skill in the art would find such terms clear and definite, claims 65, 66, 93, 94, 99, 100 and 187 have been cancelled, rendering this rejection moot. Claims 189-284 lack the terms to which the Examiner objected. The rejections under 35 USC 112, second paragraph are therefore moot.

The rejection under 35 U.S.C. 102(e)

The Examiner rejected claim 99 under 35 U.S.C. § 102(e) over U.S. Pat. No. 5,670,540 to Horrobin et al. ("'540"). Cancellation of claim 99 renders this rejection moot at this time. However, Applicants traverse the Examiner's assertions regarding '540. Applicants claim methods of producing microbial cells having an altered fatty acid profile, and methods of obtaining microbial oils and fractions thereof. '540 deals with forming triglycerides having abnormal arrangements of fatty acids that are not found in nature at all. See col. 4 lines 12-17. '540 also discusses compositions having high levels of LGG (see col. 4). Nowhere does '540 discuss expression of Δ6 desaturases in microbial cells so as to alter their fatty acid profile, or the production of oil from such cells, or the purification of a component therefrom.

CONCLUSION

Accordingly, in view of the above remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (408) 849-4908.

DATE: April 12, 2002

Respectfully submitted,

By: _____

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